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EXAMINER	
BOWERS, NATHAN ANDREW	
ART UNIT	**PAPER NUMBER**
1744	

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/756,553	SHEPARD ET AL.	
	Examiner	Art Unit	
	Nathan A. Bowers	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1) Claims 1, 3-15, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silcott (US 20030098422) in view of Dai (US 20030230728), and optionally further in view of Cramp (US 4490043).

With respect to claims 1, 3, 5-7 and 15, Silcott discloses a bioagent detecting system comprising a laser diode (Figure 3:106) for generating ultraviolet light to fluoresce an aromatic protein. This is disclosed in paragraphs [0044]-[0051]. Furthermore, a detector (Figure 4:412) and a system controller (Figure 16:1604) are provided for sensing induced fluorescence from the protein and correlating the detected fluorescence levels with atmospheric absorption levels to determine if an ambient threshold is exceeded by a predetermined amount. This is disclosed in paragraphs [0085]-[0095]. Silcott, however, does not expressly state that multiple diodes are provided in the form of a first array for generating UV light characterized by a first wavelength and a second array for generating UV light characterized by a second wavelength.

Dai discloses a bioagent detecting system and method comprising a first array (Figure 3:104a) of light emitting diodes (LED) for generating a first ultraviolet wavelength and a second array (Figure 13:104b) of LEDs for generating a second ultraviolet wavelength. This is disclosed in paragraphs [0008]-[0015] and [0032]. Paragraphs [0032]-[0037] indicate that the

individual diodes on each array may be configured to emit light at different UV wavelengths, or may be divided into separate groups that each generate light at more than one UV wavelength. A third array (Figure 3:104c) may be used to generate light at a plurality of different wavelengths. It is believed that the diode arrays disclosed by Dai are capable of generating a pair of discrete UV wavelengths in such a way that each array generates light at a separate and single wavelength. Furthermore, it is believed that Dai's invention is capable of illuminating and inducing fluorescence in a single sample using the first and second wavelengths. These limitations merely represent intended uses of the device (See MPEP 2114).

Silcott and Dai are analogous art because they are from the same field of endeavor regarding the use of a light source and a photodetector to detect fluorescence in a biological analyte.

At the time of the invention, it would have been obvious to substitute the single laser diode disclosed by Silcott with a plurality of laser diodes arranged across multiple arrays. This would allow one the ability to simultaneously and sequentially irradiate a biological sample with UV light at a plurality of different wavelength. In paragraph [0020], Dai states that this is advantageous because it allows one to easily detect fluorescence at a variety of excitation wavelengths in a quick and efficient manner. By incorporating a plurality of individually controlled laser diodes, Silcott's device would be capable of simultaneously analyzing a sample for the presence of a plurality of hazardous bioagents that fluoresce at different wavelengths.

It is noted that Applicant has amended claim 1 to include "wherein the first and second ultraviolet wavelengths comprise a pair of ultraviolet wavelengths selected to have different absorption levels for the aromatic protein which are substantially unaffected by atmospheric

levels of the aromatic protein." This statement does not further limit the claim since it, like other statements regarding the use of the device, simply describes an exemplary way in which the apparatus can be operated. However, in order to further the prosecution of the instant application, Cramp (US 4490043) is cited to show that these limitations are obvious.

Cramp discloses a method and apparatus for remotely monitoring the presence of an analyte through the air using two distinct wavelengths emitted from a light source. The selected wavelengths have different absorption levels for the analyte in question, however the atmospheric absorption levels for the wavelengths of the pair are substantially the same. In this way, a correlation between first and second emitted radiation levels with known atmospheric absorption levels can be used to determine if analytes are present. This is disclosed in column 1, lines 1-41 and in column6, lines 32-51.

At the time of the invention, it would also have been obvious to ensure that the plurality of laser diodes disclosed by Silcott and Dai are use to produce a pair of wavelengths that interact with the analyte in question differently, but exhibit similar atmospheric absorption levels. In column 1, lines 1-41 and throughout the reference, Cramp indicates that this method of use if beneficial because it allows one to "obtain the ratio of the isolated signals corresponding to radiation collected from a detection beam and a related reference beam" in order to provide an accurate measure of the analyte in a suspect cloud.

With respect to claims 4, 8, 10-12, Silcott, Dai and optionally Cramp disclose the apparatus set forth in claims 1 and 5 as set forth in the 35 U.S.C. 103 rejection above. Furthermore, Silcott teaches in Table 2 and paragraphs [0051]-[0054] that tryptophan fluoresces

at 320-350 nm, and therefore should be irradiated with UV light of 220, 280 and 288 nm. Silcott states in paragraph [0085] that anthrax is detected using the disclosed invention. Anthrax has an aromatic-protein shell comprising tryptophan, and therefore can be quantified by detecting tryptophan fluorescence. In addition, the wavelength pairs generated by the diode arrays disclosed by Dai may intrinsically be produced so that they only differ by approximately 1 to 5 nm.

With respect to claims 9, 19 and 20, Silcott, Dai and optionally Cramp disclose the apparatus set forth in claim 5 as set forth in the 35 U.S.C. 103 rejection above. In addition, Silcott states in paragraph [0071] that the detector comprises avalanche photo diodes to detect fluorescence levels. Silcott states in paragraphs [0058] and [0059] that the UV laser light is collimated by lenses. The collimator intrinsically could collimate the laser light for direction toward a suspect cloud in the atmosphere.

With respect to claims 13 and 14, Silcott, Dai and optionally Cramp disclose the apparatus set forth in claim 5 as set forth in the 35 U.S.C. 103 rejection above. In addition, Silcott teaches in paragraphs [0085]-[0095] that the system controller receives a detection signal from the detector that is proportional to the fluorescence level, and that a notification signal is generated when the detection signal indicates that a threshold is exceeded. The threshold is based on a predetermined value that corresponds to a standard condition.

2) Claims 2 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silcott (US 20030098422) in view of Dai (US 20030230728) and optionally Cramp (US 4490043) as applied to claims 1 and 15, and further in view of Engelhardt (US 20010025930).

Silcott, Dai and Cramp disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. In addition, Silcott discloses in paragraph [0071] that the detector comprises avalanche photo diodes to detect fluorescence levels. Silcott states in paragraphs [0058] and [0059] that the UV laser light is collimated by lenses. Dai teaches in paragraphs [0032]-[0037] that the diode array comprises additional groups for generating other a plurality of wavelengths which cause fluorescence. Silcott and Dai, however, do not expressly disclose that the system controller is to repeat the addressing and correlating for diodes in order to determine the presence of an analyte.

Engelhardt discloses a method for the detection and analysis of a specimen in which a laser (Figure 2:7) is used to fluoresce a sample (Figure 2:5). A detector (Figure 2:11) is provided to analyze the emitted light. This is disclosed in paragraph [0053]. Paragraphs [0026] and [0027] state that a system controller (Figure 2:15) is used to control the operation of the laser in order to radiate the sample with a plurality of different wavelengths over time. The information gathered at each of the different wavelengths by the detector is used to more completely characterize the nature of the specimen.

Silcott, Dai, Cramp and Engelhardt are analogous art because they are from the same field of endeavor regarding the use of light to produce fluorescence in a biological sample.

At the time of the invention, it would have been obvious to repeatedly analyze a sample at different wavelengths over time using the apparatus proposed by Silcott and Dai. Engelhardt

teaches that fluorescence can be detected at different wavelengths and at different times, and that the resulting information can be compared in order to more thoroughly determine the nature of the biological sample. The device proposed by Silcott and Dai is entirely capable of being used in this way, since a plurality of arrays, each comprising a plurality of diodes, are provided. Therefore, it would have been obvious to repeatedly emit UV light from the diodes and detect the subsequent fluorescence of the sample to attain more accurate and reliable results. This is especially true when using the device to determine the presence of hazardous bioagents since precise detection methods encourage safety.

3) Claims 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silcott (US 20030098422) in view of Dai (US 20030230728) and optionally Cramp (US 4490043) as applied to claims 15 and 20, and further in view of Petrich (US 20030160182).

Silcott, Dai and Cramp disclose the apparatus set forth in claims 15 and 20 as set forth in the 35 U.S.C. 103 rejections above, however do not expressly disclose that the apparatus comprises a range finder, or that the apparatus is handheld.

Petrich discloses an apparatus that comprises a plurality of light sources (Figure 4:110) that emit ultraviolet light in order to cause a hazardous bioagents upon a sample (Figure 1:140) to fluoresce. This resulting fluorescence is detected by a sensor (Figure 4:130) which relays information to a processor (Figure 4:117). This is disclosed in paragraphs [0015] and [0032]-[0038]. Petrich teaches that the device is handheld and is adapted to receive batteries. Paragraph [0039] teaches that the apparatus further includes a proximity sensor (Figure 4:122) that is capable of determining the distance to a biological sample.

Silcott, Dai, Cramp and Petrich are analogous art because they are from the same field of endeavor regarding the use of fluorescence to determine the presence of undesirable biological compounds.

At the time of the invention, it would have been obvious to construct the apparatus proposed by Silcott and Dai as a handheld device. Petrich teaches in paragraphs [0003] and [0011] that handheld devices are lightweight and portable, and are useful because they can be easily transported to any place that requires the detection of a biologically dangerous compounds. This type of portable device is necessary to analyze a suspect cloud that may materialize anywhere and at any time. Furthermore, it would have been obvious to provide the invention with a range finder. Petrich teaches in paragraph [0039] that a range finder is beneficial because it can be used to restrict UV radiation if the object to be analyzed is determined to not be within the light path or not be within a certain distance from the light source. This is advantageous because it provides increased safety to the user by reducing any unintended and unnecessary exposure to the light source.

4) Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Silcott (US 20030098422) in view of Dai (US 20030230728) and optionally Cramp (US 4490043) as applied to claim 5, and further in view of Reichert (US 6911344) or Giebeler (6313471).

Silcott, Dai and Cramp disclose the apparatus set forth in claim 5 as set forth in the 35 U.S.C. 103 rejection above. Silcott discloses tunable fiber lasers, however do not disclose that a blaze grating is used to receive multiple wavelength light from the array of diodes and direct a selected wavelength through an output coupler.

Reichert and Giebeler disclose apparatuses for facilitating fluorescence detection of biological compounds. Reichert states in column 2, line 64 to column 3, line 41 that blaze gratings and output couplers are known in the art as effective ways to select a desired wavelength. Giebeler discloses the use of blaze gratings in column 6, lines 9-24 and in column 8, lines 29-45.

Silcott, Dai, Cramp, Reichert and Giebeler are analogous art because they are from the same field of endeavor regarding fluorescent detection procedures.

At the time of the invention, it would have been obvious to add a blaze grating and an output coupler to the apparatus disclosed by Silcott and Dai. Blaze gratings and output couplers are well known in the art and are effective mechanisms to direct light of a desired wavelength to a detector. Multi-wavelength light derived from the laser disclosed by Silcott could easily be manipulated using a blaze grating and an output coupler based on a control signal from a system controller.

5) Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Silcott (US 20030098422) in view of Dai (US 20030230728) and Cramp (US 4490043).

Silcott and Dai disclose the combination as previously described above. However, Silcott and Dai do not expressly teach using the disclosed first and second ultraviolet wavelengths to fluoresce the same aromatic protein. Dai indicates a method in which the different wavelengths are used to fluoresce different dyes. Silcott and Dai do not expressly teach the use of a pair of wavelengths with different absorption levels for the same biological component and similar atmospheric absorption levels.

Cramp discloses a method and apparatus for remotely monitoring the presence of an analyte through the air using two distinct wavelengths emitted from a light source. The selected wavelengths have different absorption levels for the analyte in question, however the atmospheric absorption levels for the wavelengths of the pair are substantially the same. In this way, a correlation between first and second emitted radiation levels with known atmospheric absorption levels can be used to determine if analytes are present. This is disclosed in column 1, lines 1-41 and in column6, lines 32-51.

At the time of the invention, it would also have been obvious to ensure that the plurality of laser diodes disclosed by Silcott and Dai are use to produce a pair of wavelengths that interact with the analyte in question differently, but exhibit similar atmospheric absorption levels. In column 1, lines 1-41 and throughout the reference, Cramp indicates that this method of use if beneficial because it allows one to "obtain the ratio of the isolated signals corresponding to radiation collected from a detection beam and a related reference beam" in order to provide an accurate measure of the analyte in a suspect cloud.

6) Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silcott (US 20030098422) in view of Dai (US 20030230728) and Cramp (US 4490043) as applied to claim 24, and further in view of Engelhardt (US 20010025930).

Silcott, Dai and Cramp disclose the method set forth in claim 24 as set forth in the 35 U.S.C. 103 rejection above. In addition, Silcott discloses in paragraph [0071] that the detector comprises avalanche photo diodes to detect fluorescence levels. Silcott states in paragraphs [0058] and [0059] that the UV laser light is collimated by lenses. Dai teaches in paragraphs

[0032]-[0037] that the diode array comprises additional groups for generating other a plurality of wavelengths which cause fluorescence. Silcott, Dai and Cramp, however, do not expressly disclose that the system controller is to repeat the addressing and correlating for diodes in order to determine the presence of an analyte.

Engelhardt discloses a method for the detection and analysis of a specimen in which a laser (Figure 2:7) is used to fluoresce a sample (Figure 2:5). A detector (Figure 2:11) is provided to analyze the emitted light. This is disclosed in paragraph [0053]. Paragraphs [0026] and [0027] state that a system controller (Figure 2:15) is used to control the operation of the laser in order to radiate the sample with a plurality of different wavelengths over time. The information gathered at each of the different wavelengths by the detector is used to more completely characterize the nature of the specimen.

Silcott, Dai, Cramp and Engelhardt are analogous art because they are from the same field of endeavor regarding the use of light to produce fluorescence in a biological sample.

At the time of the invention, it would have been obvious to repeatedly analyze a sample at different wavelengths over time using the method proposed by Silcott and Dai. Engelhardt teaches that fluorescence can be detected at different wavelengths and at different times, and that the resulting information can be compared in order to more thoroughly determine the nature of the biological sample. The method proposed by Silcott and Dai is entirely capable of being altered in this way, since a plurality of arrays, each comprising a plurality of diodes, are provided. Therefore, it would have been obvious to repeatedly emit UV light from the diodes and detect the subsequent fluorescence of the sample to attain more accurate and reliable results.

This is especially true when using the device to determine the presence of hazardous bioagents since precise detection methods encourage safety.

Response to Arguments

All previous rejections stated in the first Office Action (2/16/06) under 35 U.S.C. 112 have been withdrawn in light of Applicant's amendments.

Applicant's arguments filed 26 April 2006 with respect to the 35 U.S.C. 103 rejection of claim 1 involving Silcott in view of Dai have been fully considered but they are not persuasive.

Applicant's principle arguments are

(a) Applicant's invention comprises first and second ultraviolet wavelengths that are selected to fluoresce the same aromatic protein. Dai, on the other hand, uses the different wavelengths for different dyes. Furthermore, Dai does not teach generating wavelengths of a pair and detecting the resultant fluorescent levels. Silcott and Dai do not use different wavelengths with different absorption levels for the same biological components. The wavelengths of each pair must also have similar atmospheric absorption levels.

In response to Applicant's arguments, please consider the following comments.

It is agreed that Silcott and Dai do not expressly disclose a method in which a pair of wavelengths simultaneously fluoresce the same biological analyte. It is also true that Dai does not expressly disclose that the different wavelengths have different analyte absorption levels and similar atmospheric absorption levels. However, it is believed that these claim limitations merely represent an intended use. Silcott and Dai's combined invention could be used in this

way since the combination discloses all of the positively stated structural limitations, such as first and second laser diode groups, a detector, and a system controller. See MPEP 2115.

In response to argument that Silcott and Dai do not teach the generation of wavelength pairs having different protein absorption levels, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Furthermore, the Cramp reference has been cited to indicate that the generation of different wavelengths having different analyte absorption levels and similar atmospheric absorption levels is known in the optical detection art.

Applicant's arguments, see pages 9-13, filed 26 April 2006, with respect to the rejection(s) of claim(s) 24 under 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Silcott, Dai and Cramp.

The Cramp reference has been added to indicate that the use of a pair of wavelengths selected to have different absorption levels fort the analyte to be detected is known in the art. Cramp discloses a multi-wavelength detection system in which the atmospheric absorption levels for the wavelengths of each pair are substantially the same.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NAB

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SUPERVISORY PATENT EXAMINER